

IN THE CLAIMS:

*GWD* 1. A method of applying energy to cause shrinkage of a vein lumen, the method comprising the steps of:

introducing a catheter having a working end with an energy application apparatus located at the working end, to a treatment site in the vein lumen;

5 positioning the energy application apparatus adjacent the treatment site in the vein lumen;

directionally emitting energy from the energy application apparatus to selectively heat the treatment site and cause shrinkage of venous tissue at the treatment site; and

10 terminating the emission of energy from the energy application apparatus after shrinking the vein to restore valvular competency while maintaining venous patency.

2. The method of claim 1 further comprising the step of determining the occurrence of shrinkage of the vein using fluoroscopy.

3. The method of claim 1 wherein the step of positioning the energy application apparatus at the treatment site further includes the step of placing the energy application apparatus at a commissure of a venous valve of the treatment site.

4. The method of claim 3 further including the step of positioning the energy application apparatus adjacent leaflets of the valve, after the step of placing the energy application apparatus at the commissure of the venous valve of the treatment site.

5. The method of claim 1 wherein the step of directionally emitting energy further includes the step of producing at least two discrete RF fields at the working end of the catheter by the energy application apparatus to directionally heat at least two separated venous sites at the treatment site simultaneously.

6. The method of claim 1 wherein the step of directionally emitting energy further includes the step of producing a discrete RF field along a portion of the circumference of the catheter by the energy application apparatus to directionally heat the venous tissue.

7. The method of claim 6 wherein the step of producing the discrete RF field includes the step of positioning the catheter to treat the commissure of the venous valve, and then the leaflets of the venous valve.

8. The method of claim 1 wherein the step for directionally emitting energy comprises the step of passing radio frequency energy between a positive polarity electrode and a negative polarity electrode to create an RF field along a portion of the catheter.

9. The method of claim 1 wherein the step of directionally emitting energy comprises the step of directionally emitting optical energy to selectively heat the treatment site.

10. The method of claim 9 wherein the step of directionally emitting optical energy comprises the further step of reflecting optical energy at the working end of the catheter to create a directional emission of energy for selectively heating the treatment site.

11. The method of claim 1 further comprising the step of palpating the vein into apposition with the energy application apparatus of the catheter in the vein lumen.

12. The method of claim 1 further comprising the steps of locating the working end of the catheter in apposition with the vein wall adjacent a selected commissure and directionally emitting energy to the vein wall to shrink the commissure.

13. The method of claim 1 further comprising the step of expanding the energy application apparatus radially outward from the working end and into apposition with the vein wall and directionally emitting energy to the vein wall to cause preferential shrinkage of venous tissue at the wall.

14. The method of claim 13 wherein the step of expanding comprises the step of expanding at least two pairs of electrodes from the working end into apposition with the vein wall, wherein each pair of electrodes comprises a discrete pair of opposite

5 polarity electrodes and the electrodes within each discrete pair are arranged such that an electrode in one discrete pair is adjacent a like polarity electrode of the adjacent pair.

15. The method of claim 14 wherein the step of expanding comprises the step of expanding an even number of electrodes into apposition with the vein wall, wherein said even number comprises at least four, and wherein said even number of electrodes are disposed in a plurality of discrete pairs of opposite polarity electrodes, said electrodes 5 in each discrete pair being arranged such that an electrode in one discrete pair is adjacent a like polarity electrode of an adjacent pair.

16. The method of claim 1 further comprising the step of determining the occurrence of shrinkage of the vein using ultrasonographic imaging.

17. The method of claim 1 wherein the step of positioning the energy application apparatus at the treatment site further includes the step of placing the energy application apparatus at an ostium and applying energy to reduce the size of the ostium.

18. A method of applying energy to cause the shrinkage of a vein to restore valvular competency, the method comprising the steps of:

introducing a catheter having a working end and at least two electrodes located at the working end, to a treatment site in the vein;

5 positioning the at least two electrodes adjacent venous tissue at the treatment site in the vein;

applying high frequency energy from the electrodes to heat the treatment site and cause shrinkage of the vein; and

terminating the application of energy from the electrodes after shrinking the 10 venous tissue so that valvular competency is restored and patency of the vein is maintained.

19. The method of claim 18 further comprising the step of determining the occurrence of shrinkage of the vein using fluoroscopy.

20. The method of claim 18 further comprising the step of determining the occurrence of shrinkage of the vein using ultrasonographic imaging.
21. The method of claim 18 wherein the step of applying high frequency energy further includes the step of applying radio frequency energy between the at least two electrodes.
22. The method of claim 18 wherein the step of emitting high frequency energy further includes the step of producing a discrete RF field along a portion of the circumference of the catheter to directionally heat the venous tissue.
23. The method of claim 22 wherein the step of producing the discrete RF field includes the step of positioning the catheter to treat the commissures of the venous valve, and then the leaflets of the venous valve.
24. The method of claim 18 wherein the step of positioning the at least two electrodes at the treatment site further includes the step of placing the at least two electrodes at a commissure of the venous valve of the treatment site.
25. The method of claim 24 further including the step of placing the electrodes adjacent the leaflets of the valve after the step of placing the electrodes at the commissure of the venous valve of the treatment site.
26. The method of claim 18 wherein the step of emitting energy further includes the step of producing at least two discrete RF fields along the circumference of the catheter to directionally heat the venous tissue so that both commissures of the venous valve at the treatment site can be treated simultaneously.
27. The method of claim 18 further comprising the step of extending the electrodes away from the catheter to increase the effective diameter of the catheter.

28. The method of claim 27 further comprising the step of deploying an expandable member coupled to the working end to selectively position the two electrodes against selected venous tissue.

29. The method of claim 28 wherein the step of extending comprises the step of expanding at least two pairs of electrodes from the working end into apposition with the vein wall, wherein each pair of electrodes comprises a discrete pair of opposite polarity electrodes and the electrodes within each discrete pair are arranged such that an 5 electrode in one discrete pair is adjacent a like polarity electrode of the adjacent pair.

30. The method of claim 29 wherein the step of expanding comprises the step of expanding an even number of electrodes into apposition with the vein wall, wherein said even number comprises at least four, and wherein said even number of electrodes are disposed in a plurality of discrete pairs of opposite polarity electrodes, said electrodes 5 in each discrete pair being arranged such that an electrode in one discrete pair is adjacent a like polarity electrode of an adjacent pair.

31. The method of claim 18 further comprising the step of palpating the vein into apposition with the electrodes of the catheter in the vein lumen.

32. The method of claim 18 further comprising the steps of locating the working end of the catheter in apposition with the vein wall adjacent a selected commissure and directionally emitting energy to the vein wall to shrink the commissure.

33. The method of claim 18 wherein the step of positioning the energy application apparatus at the treatment site further includes the step of placing the energy application apparatus at an ostium and applying energy to reduce the size of the ostium.

*Subj* (34.) An apparatus for applying energy to cause shrinkage of a vein, the apparatus comprising:

a catheter having a shaft with an outer diameter and a working end, wherein the outer diameter of the catheter is less than the inner diameter of the vein; and

at least two electrodes located at the working end of the catheter, wherein the electrodes are spaced apart from one another so as to produce a directional RF field to heat a venous treatment area adjacent the electrodes to cause preferential shrinkage of the vein when RF energy is applied to the vein by the electrodes.)

35. The apparatus of claim 34 further comprising a piezoelectric element located adjacent the electrodes, the piezoelectric element producing pulse-echo soundings of the vein to determine the vein diameter and the extent of vein shrinkage.

36. The apparatus of claim 34 further comprising a temperature sensor located on one of the at least two electrodes.

37. The apparatus of claim 34 further comprising a temperature sensor located between the two electrodes.

38. The apparatus of claim 34 wherein the catheter includes a plurality of extendable members having a plurality of bowable sections, each bowable section including one of the at least two electrodes.

39. The apparatus of claim 34 further comprising:  
an outer tube having a first end and a second end, the outer tube surrounding the catheter shaft;

a tip member located at the working end of the catheter shaft;  
5 at least two bowable members, each bowable member having a first mounting end attached to the second end of the outer tube, a second mounting end attached to the tip, and one of the at least two electrodes between the first and second mounting ends;

wherein the outer tube moves over the catheter shaft, and the electrodes move away from the catheter shaft when the second end of the outer tube moves toward the  
10 tip.

40. The apparatus of claim 39 further comprising a cover connecting the second end of the outer tube to the tip, wherein the cover prevents fluid from seeping between the outer tube and the catheter shaft.

- (41.) The apparatus of claim 40 wherein the cover comprises a bellows.
  - (42.) The apparatus of claim 40 wherein the cover is generally elastic.
  - (43.) The apparatus of claim 34 wherein the working end of the catheter has a diameter larger than the diameter of the remainder of the catheter.
44. The apparatus of claim 34 wherein the working end of the catheter further includes ports for providing a fluid to the vein during treatment.
45. The apparatus of claim 34 wherein the catheter further comprises a positioning device disposed such that activating the positioning device controls the position of the working end of the catheter, whereby the working end may be selectively positioned at venous tissue sites.
46. The apparatus of claim 45 wherein the positioning device is located on the opposite end of shaft from the electrodes to position the electrodes into contact with venous tissue to be treated.
47. The apparatus of claim 46 wherein the catheter comprises an inflation lumen, the positioning device comprises an inflatable balloon disposed at the working end in fluid communication with the inflation lumen such that the inflation of the balloon may be controlled through fluid in the inflation lumen.
- (48.) The apparatus of claim 34 wherein the electrodes are formed from non-insulated portion of a metallic plate disposed in the working end of the catheter.
  - (49.) The apparatus of claim 48 wherein the electrodes are formed into pairs, wherein each pair of electrodes comprises a discrete pair of opposite polarity electrodes and the electrodes within each discrete pair are arranged such that an electrode in one discrete pair is adjacent a like polarity electrode of an adjacent pair.

50. The apparatus of claim 49 comprising an even number of electrodes, wherein said even number comprises at least four, and wherein said even number of electrodes are disposed in a plurality of discrete pairs of opposite polarity electrodes at the working end, said electrodes in each discrete pair being arranged such that an 5 electrode in one discrete pair is adjacent a like polarity electrode of an adjacent pair.

51. The apparatus of claim 34 further comprising an ultrasonographic imaging apparatus disposed so as to determine the occurrence of shrinkage of the vein.

52. The apparatus of claim 34 wherein the electrodes are formed of a material that produces heat upon the application of selected energy to the electrodes.

53. An apparatus for applying energy to cause shrinkage of a vein, the apparatus comprising:

a catheter having a shaft, an outer diameter and a working end, wherein the outer diameter of the catheter is less than the inner diameter of the vein; and

5 a directional energy application apparatus located at the working end and adapted to deliver energy to a venous treatment area adjacent the working end of the catheter to cause shrinkage of the vein along a circumferential portion of the vein.

54. The apparatus of claim 53 further comprising a piezoelectric element located on the catheter adjacent the directional energy application apparatus producing pulse-echo soundings of the vein to determine the vein diameter and the extent of vein shrinkage.

55. The apparatus of claim 53 wherein the working end of the catheter has a diameter larger than the diameter of the remainder of the catheter.

56. The apparatus of claim 53 wherein the working end of the catheter further includes a port for providing a fluid to the vein during treatment.

57. The apparatus of claim 53 wherein the catheter further comprises a positioning device such that activating the positioning device controls the position of the

working end of the catheter, whereby the working end may be selectively positioned at venous tissue sites.

58. The apparatus of claim 57 wherein the positioning device is located on the opposite side of the shaft from the directional energy application apparatus to position the directional energy application apparatus into contact with venous tissue to be treated.

59. The apparatus of claim 58 wherein the catheter comprises an inflation lumen, the positioning device comprises an inflatable balloon disposed at the working end in fluid communication with the inflation lumen such that the inflation of the balloon may be controlled through fluid in the inflation lumen.

60. The apparatus of claim 53 wherein the directional energy application apparatus includes a non-insulated portion of a metallic plate disposed in the working end of the catheter.

61. The apparatus of claim 53 wherein the electrodes are formed of a material that produces heat upon the application of selected energy to the electrodes.

62. The apparatus of claim 53 wherein the directional energy application apparatus comprises a device providing optical energy.

63. The apparatus of claim 62 further comprising:  
a source of optical energy;  
a conducting device conducting optical energy from said source to said working end; and

5 a radiating device located at said working end for directing said optical energy from the catheter in a selected direction.

64. The apparatus of claim 63 wherein the radiating device comprises an optical reflector located at the working end and disposed to directionally emit optical energy from the working end.

65. The apparatus of claim 53 wherein the directional energy application apparatus comprises at least two pairs of electrodes disposed at the working end, wherein each pair of electrodes comprises a discrete pair of opposite polarity electrodes and the electrodes within each discrete pair are arranged such that an electrode in one discrete pair is adjacent a like polarity electrode of an adjacent pair.

66. The apparatus of claim 65 wherein the directional energy application apparatus comprises an even number of electrodes, wherein said even number comprises at least four, and wherein said even number of electrodes are disposed in a plurality of discrete pairs of opposite polarity electrodes at the working end, said electrodes in each discrete pair being arranged such that an electrode in one discrete pair is adjacent a like polarity electrode of an adjacent pair.

67. *not shown* The apparatus of claim 53 further comprising an ultrasonographic imaging apparatus disposed so as to determine the occurrence of shrinkage of the vein.

68. An apparatus for applying energy to biological tissue, comprising:  
a catheter having an elongated body with a distal end and a proximal end;  
at least four exposed, electrically conductive surfaces located at the distal end of the catheter; and

5 a plurality of electrically conductive lines electrically connected to the exposed surfaces having a length such that they extend to the proximal end of the catheter from the exposed surfaces;

10 wherein the exposed surfaces are disposed so that each exposed surface is located adjacent another exposed surface of like polarity and adjacent another exposed surface of unlike polarity;

whereby energy imparted by a pair of exposed surfaces of unlike polarity is directional.

69. The apparatus of claim 68 further comprising a positioning device located at the working end of the catheter that is selectively actuatable so as to position the conducting surfaces at a selected biological tissue site.

70. The apparatus of claim 69 wherein the positioning device comprises an inflatable balloon disposed on the catheter body opposite the conducting surfaces.

71. The apparatus of claim 69 wherein the positioning device comprises an expandable strut disposed on the catheter body opposite the conducting surfaces, wherein the strut may be moved outwardly from the catheter body and moved inwardly toward the catheter body.

(72.) The apparatus of claim 68 wherein the positioning device comprises a control wire attached to the distal end of the catheter and disposed within the catheter such that changing its tension controls the deflection of the catheter distal end.

(73.) The apparatus of claim 68 further comprising an energy source having two potentials, one of which is connected to two exposed surfaces through a conductive device and the other of which is connected to the other two exposed surfaces through another conductive device.

(74.) The apparatus of claim 68 wherein the exposed surfaces are disposed at the distal end of the catheter as discrete pairs with each pair comprising one surface of one polarity and another surface of a different polarity;

wherein the pairs are disposed in relation to each other so that the exposed  
5 surface of an adjacent pair is of like polarity.

75. The apparatus of claim 68 further comprising a temperature sensor located on one of the electrodes.

76. The apparatus of claim 68 further comprising a temperature sensor located between two electrodes.

(77.) The apparatus of claim 68 wherein the catheter includes a plurality of extendable members having a plurality of bowable sections, each bowable section including one of the electrically conductive surfaces.

- (78.) The apparatus of claim 68 further comprising:  
an outer tube having a first end and a second end, the outer tube surrounding the catheter shaft;  
a tip member located at the working end of the catheter shaft;  
5 at least two bowable members, each bowable member having a first mounting end attached to the second end of the outer tube, a second mounting end attached to the tip, and having one of the electrically conductive surfaces located between the first and second mounting ends;  
wherein the outer tube moves over the catheter shaft, and the electrically  
10 conductive surfaces move away from the catheter shaft when the second end of the outer tube moves toward the tip.

(79.) The apparatus of claim 78 further comprising a cover connecting the second end of the outer tube to the tip, wherein the cover prevents fluid from seeping between the outer tube and the catheter shaft.

- (80.) The apparatus of claim 79 wherein the cover is generally elastic.  
(81.) The apparatus of claim 79 wherein the cover comprises a bellows.  
*With claim 78*  
(82.) The apparatus of claim 68 further comprising an ultrasonographic imaging apparatus disposed so as to determine the occurrence of shrinkage of the vein.

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